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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michitaka Sato

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EXAMINER

LEESER, ERICH A

ART UNIT

PAPER NUMBER

1624

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,707	Applicant(s) SATO ET AL.	
	Examiner Erich A. Leeser	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-16 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 8-11, 13, 15, 18-22 and 25 is/are rejected.
- 7) ☒ Claim(s) 3-5, 12, 14, 16, 23-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-8-09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This action is in response to Applicant's submission dated April 29, 2009 in which Applicant amended claims 18-22 and cancelled claim 17. Claims 1-6, 8-16, and 18-25 are pending and under examination.

Information Disclosure Statement

The references contained in the IDS dated May 8, 2009, are made of record.

Claim Rejections 35 U.S.C. § 103

Examiner previously rejected claims 1-2, 9-11, 13 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Matsuoka, et al., Canada Patent No. 2431406.

Applicant has provided comparable compounds and argues that the instant compounds provide superior results over the compounds of the reference. Examiner disputes the validity of this comparison as Table 2 shows that the dose of TZB41044 was three times that of the three compared compounds without any explanation from Applicant as to this deviation in standard chemical comparison. Even if this major dosage discrepancy is overlooked by a fact finder the actual numerical variation between LLR, FBP, and BT are not that great between TZB41044 and the three compared compounds.

This rejection is now moot with regards to cancelled claim 7. As such, Examiner maintains this rejection over claims 1-2, 9-11, 13 and 15 for the reasons of record.

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Claim Rejections - 35 USC § 112

Examiner previously rejected claims 17 and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Based on Applicant's cancellation of claim 17 and amendment of claim 22, Examiner withdraws this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because while enabling for pyrimidine derivatives of formula (I) in which ring A is saturated, unsaturated or partially saturated carbohexyl group; X₁ is amino or methyl; X₁ is hydrogen; Y is a direct bond; n is 3; and Ar is the group represented by the second formula listed, the specification does not enable the instant compounds to treat irritable bowel syndrome (IBS) with compounds of any other permutation of formula (I) or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

This rejection is now moot with regards to cancelled claim 17.

Applicant argues that Examiner only considered Table D of the specification when making the rejection. Applicant considered the entire specification, including Table A-1 on pages 48-49, when making the rejection.

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As such, Examiner maintains the rejection over claims 18-22 and 25 for reasons of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-10, and 15 are rejected under 35 USC 102(b) as being anticipated by Arita, et al., EP 0 364 598. Arita, et al. teaches 3,4-dihydrothieno[2,3-d]pyrimidine compounds, which include instant compounds. Specifically, the compound Example No. 41 of the reference anticipates the aforementioned claims where X¹ is phenyl substituted with chloro, A is heterocyclic group substituted with SO₂NH₂, Y is a direct bond, n is 0, X² is hydrogen, and Ar is the first choice (pyridine). The closest example to Example No. 41 of the reference is Example 23 found on instant page 162. Therefore, the instant claims 1, 9-10, and 15 are anticipated by Arita, et al., EP 0 364 598.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1, 6, 8-11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Modica, et al., *[[Arylpiperazinyl)alkyl]thio]thieno[2,3-d]pyrimidinone Derivatives as High-Affinity, Selective 5-HT_{1A} Receptor Ligands*, J. Med. Chem. 40, 574-585 (1997).

Determining the scope and contents of the prior art.

Ashkinazi, et al. teaches 5H-pyrano[2,3-D: 6,5D']dipyrimidine core containing compounds. Specifically, the compounds 72-73 of the reference renders obvious the aforementioned claims where X¹ is amino or methyl, A is heterocyclic group di-substituted with methyl, Y is sulfur, n is 2, X² is hydrogen, and Ar is pyrimidine.

Ascertaining the difference between the prior art and the claims at issue.

It is well-established that position isomers are *prima facie* structurally obvious even in the absence of a teaching to modify. The isomer is expected to be made by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This situation has arisen many times in the courts. *Ex parte Englehardt*, 208 USPQ 343, 349; *In re Mehta*, 146 USPQ 284, 287; *In re Surrey*, 138 USPQ 67; *Ex Parte Ullyot*, 103 USPQ 185; *In re Norris*, 84 USPQ 459; *Ex Parte Naito*, 168 USPQ 437, 439; *Ex parte Allais*, 152 USPQ 66; *In re Wilder*, 166 USPQ 545, 548; *Ex parte Henkel*, 130 USPQ 474; *Ex parte Biel*, 124 USPQ 109; *In re Petrzilka*, 165 USPQ 327; *In re Crownse*, 150 USPQ 554; *In re Fouche*, 169 USPQ 431; *Ex parte Ruddy*, 121 USPQ 427; *In re Wiechert*, 152 USPQ 247, *In re Shetty*, 195 USPQ 753; *In re Jones*, 74 USPQ 152, 154; and *In re Mayne*, 41

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USPQ2d 1451, 1454-1455 (the court took notice of the extreme similarity between the amino acids Leucine and isoleucine: “In fact, Leu is an isomer of Ile -- an identical chemical formula with differences only in the chemical bonding of the atoms. The side chains ... of Leu and Ile have the same number of hydrogen and carbon atoms.... The structure of Leu and Ile alone suggest their functional equivalency”).

For example, “Position isomerism has been used as a tool to obtain new and useful drugs”, *Ex parte Englehardt*, 208 USPQ 343, 349, and: “Position isomerism is a fact of close structural similarity”. *In re Mehta*, 146 USPQ 284, 287. “Particular types or categories of structural similarity without more, have, in past cases, given rise to *prima facie* obviousness”; one of those listed is “adjacent homologues and structural isomers”. *In re Jones*, 21 USPQ2d 1942, 1943. Position isomers are the basic form of close “structural isomers.” “[A] novel useful chemical compound which is homologous or isomeric with compounds of the prior art is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compounds.” *In re Schechter and LaForge*, 98 USPQ 144, 150. “Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds ... a known compound may suggest its analogs or isomers, either geometric isomers (cis v. trans) or position isomers (e.g., ortho v. para).” *In re Deuel* 34 USPQ2d 1210, 1214. See also MPEP 2144.09, second paragraph.

Here, the only difference between the cited compounds and the instant compounds is that R of compounds 72-73 is 2-pyrimidinyl whereas Ar of the instant compounds is 4-pyrimidinyl.

Resolving the level of skill in the art.

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It would have required little more than routine modification of the synthesis of compounds 72-73 by one having ordinary skill in this art at the time the invention was made to prepare a compound within the scope of the compounds instantly claimed as Applicant has done with the above-cited reference before them. The variants show the interchangeability of the overlapping substituents.

Claim Objections

Claims 3-5, 12, 14, and 16, and 23-24 are objected to as being dependent upon a rejected independent claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

Patent Examiner, Art Unit 1624

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